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| 09/638,102 | 08/11/2000 | David C. Schwartz | 960296.97133 | 7761 |

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| EXAMINER |
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DAVIS, DEBORAH A

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 01/07/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/638,102

Applicant(s)

SCHWARTZ, DAVID C.

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 36 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-13, 34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's cancellation of claim 22 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "A chemical screening kit" which is subject matter that is not described in the specification as filed. Applicant directed the examiner's attention to page 10, lines 6-13 which describes a chemical apparatus and not the components of a kit. Applicant is invited to show support in the specification of "A chemical screening kit".

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1641

4. Claims 2-13 and 34-36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 2-13 recites the limitation "A chemical screening apparatus" in line 1. There is insufficient antecedent basis for this limitation in the claim. The preamble of claim 1 recites "A chemical screening kit" and claims 2-13 recites "A chemical screening apparatus", which does not support the limitations of a kit.

6. Claims 34-36 recites the limitation "the filaments" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 3, 6, 7, 9, 34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (USP# 4,867,946).

Gross et al anticipates the instant claims by teaching a device for evaluating test strips used to screen a variety of different samples. The test strips contain several test sections where the reagents are placed for testing (col. 1, 2nd para and see Figure 2).

Art Unit: 1641

The device has a platform and a holder to support the test strips (col 2, see claim 1) in a parallel relationship in which the test strips are perpendicular to the holder (see Figure 2). The test strip has test sections spaced along the strips to allow samples to be deposited (see Figure 2). The limitation "support frame holding the plurality of different filaments for mutual exposure to a material to be screened" as recited in claims 1, 34, and 36 will not be given patentable weight because it is intended use.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al (USP# 4,867,946) in view of Stuelpnagel et al (USP#6,396,995).

The teachings of Gross et al are set forth above and differ in the instant invention because it does not specifically point out that the organic compounds used are from the groups of oligonucleotides and peptides and that the substrate is of glass fiber.

Stuelpnagel et al teaches an optical imaging system that contains an array of multiple fiber optic bundle strips (see figure in abstract). In the detailed description of the preferred embodiments, a variety of bioactive agents are used in this optical system

Art Unit: 1641

(col. 12, lines 26-32) such as oligonucleotides, polypeptides, proteins etc. (col. 11 paras. 4 and 5) and substrates, such as glass, are used and well known in the art (col. 8, lines 45-50). A variety of bioactive agents are used to provide a sufficient range of binding to target analytes (col. 12, lines 26-32).

It would have been obvious to one of ordinary skill in the art to incorporate a variety of bioactive agents of Stuelpnagel et al in the screening device of Gross et al to have a sufficient range of binding to target analytes.

11. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Bensten et al (USP#6,372,895).

The teachings of Gross et al are set forth above and differ in the instant invention because it does not teach strips that include a marker selected from the group of printing and fluorescent material nor the use of organic compounds.

However, Bentsen et al teaches in one of his embodiments an apparatus that uses a test strip that contains a printed barcode wherein the printed material on the barcode has an enzyme or spore. The strip is further sterilized and dipped into a buffer solution containing Fluorescence Enzyme Substrate (FES). If enzyme activity is present, the printed pattern will become detectable (col. 20, lines 66-67 and col. 21, 1st para).

It would have been obvious to one of ordinary skill in the art to have incorporate the printed barcode as taught by Bentsen et al into the strips of Gross et al to detect enzyme activity. With respect to claim 5, "wherein the non-reactive strip is a glass fiber"

Art Unit: 1641

constitute an obvious variation in design that is routinely modified in the art and which have not been described as critical to the practice of the invention, especially since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. In re Stevens, 101 USPQ 284 (CCPA 1954).

Allowable Subject Matter

12. Claims 8 and 35 are allowed.

13. The following is a statement of reasons for the indication of allowable subject matter: The prior art neither teaches nor suggest that filaments or strips in the instant claims include isolating bands of chemically repellant coating between the chemically reactive substances.

14. Claims 8 and 35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

15. Applicant's argument that Gross et al no longer anticipate the invention of the claims as amended and that the claims have been amended to focus on the kit aspect

Art Unit: 1641

of the present invention is not found persuasive. The preamble of independent claim 1 recites a kit, but the limitations of the dependent claims are directed to a chemical screening apparatus. The applicant directs the examiner attention to page 10, lines 6-13 of the specification for support of a kit; but no such support is found.

16. Applicant's argument that Gross et al does not describe filaments in claim 1 is not found persuasive. Throughout the specification, "strip and filament" are used synonymously. The term "strip" is defined as any long thin member providing substantially a single dimension of locations (page 8, line32 and page 9, lines 1-2), therefore the Gross et al reference meets the limitations of the claims and the 102 rejection is maintained.

17. Applicant's arguments that Stuelpnagel teaches away from the combination because the bundling of the fiber optics would interfere with reactions and analyses of reactive substances placed along the length of the fibers have been considered but not found persuasive. The Stuelpnagel reference was relied upon for the teaching of number of possible substrates that are known in the art, such as glass, plastics acrylics (col. 8, lines 45-50) and also the variety of bioactive agents that can be attached to those substrates such as oligonucleotides, polypeptides and proteins (col. 12, lines 26-32) that are well known in the art. Therefore, the 103 rejection of Gross et al in view of Stuelpnagel is maintained for claims 4 and 5.

Art Unit: 1641

18. Applicant's belief that Bensten et al provides no teaching or suggestion for placing a marker on the claimed multiple strips in the holder of the Gross teaching is acknowledged but not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the utility of the barcode on the strips of Bensten et al provides the motivation of determining enzyme activity, (col. 20, lines 66-67 and col. 21, 1st para.) and such teachings can be modified into the present invention of Gross et al. Therefore, the 103 rejection of Gross et al in view of Bensten is maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1641

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

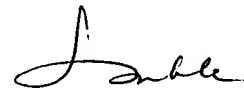
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.



Deborah A. Davis
CM1, 7D16
December 30, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/30/02